DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Memorandum

Date MAY 31 1996

From Deputy Director for Science, Center for Devices and Radiological Health (CDRH)

Subject **Standard Operating Procedures for the Development and Use of CDRH Guidance Documents**

To CDRH Staff

Purpose

The purpose of this memorandum is to establish interim procedures for the proper development and use of CDRH guidance documents while the Agency formulates its strategy for dealing with this important issue.

Background

In a citizen petition which was recently submitted by the Indiana Medical Devices Manufacturers Council, Incorporated, concerns regarding the way in which the Agency develops and uses guidance documents were expressed. Briefly, the petitioners requested that FDA institute greater controls over the initiation, development, and issuance of guidance documents to ensure that there is an appropriate level of meaningful, public participation during the developmental process. In addition, representatives of the regulated industry argued that FDA staff have not always been clear or consistent in their interpretation and application of guidance documents during the evaluation of regulatory submissions. Finally, the petitioners stated that FDA staff treat guidance documents as binding documents which set absolute requirements with no room for substitutions or modifications.

In response to these criticisms, the Agency is in the process of formulating procedures in order to standardize the developmental process by which guidance documents are created and to ensure that the opportunity for public input into the process is appropriately provided. The Agency has also committed to educating its staff as to the proper use of guidance documents when interacting with the regulated industry. The procedures outlined below were developed to standardize the CDRH guidance document development process and clarify the intent of CDRH guidances. Implementation of these procedures should serve to aid the Agency in this effort. These procedures may be superseded, however, by those ultimately developed by the Agency.

Procedures

A. Applicability

For purposes of this document, the term "guidance document" refers to documents prepared for CDRH staff and/or the regulated industry which relate to: (1) the processing, content, and evaluation of regulatory submissions, (2) the design, production, manufacturing, and testing of regulated products, and (3) inspection and enforcement procedures.

B. Procedures for the Development of CDRH Guidance Documents

In order to provide for a standard guidance document developmental process which affords sufficient opportunity for comment by parties both inside and outside the Agency, the procedures below will be implemented.

1) Upon completion of a draft guidance document, including internal review by other appropriate offices within CDRH and the Agency, the author(s) of the document should meet with division management to discuss whether comment from outside parties should be solicited. When making this decision, management should consider the potential impact that the guidance document may have on the public, including consumer interest groups, device manufacturers, and health care professionals. That is, the amount of public participation to be solicited, if any, should be determined by the type of guidance document that is being developed and the potential effect its issuance and use will have.

   To aid staff in this important decision, a decision tree has been developed (*See* Attachment A). For guidance documents which simply capture current practices or procedures, comment from outside the Office or Center is not needed. For example, a policy which prescribes administrative procedures for processing incoming correspondence would not need outside input. Also, a guidance document specifying the information expected in a 510(k) for a particular type of device would not require outside comment as long as the document did not identify new safety and effectiveness issues for that device type or suggest new or unanticipated tests involving the device. Similarly, the guidance document entitled, "Documentation Required for Preamendment Status" specifies the basic information that an applicant should submit to demonstrate the preamendments status of a medical device. Because this document simply captured longstanding policy for the Office (since 1976) and did not incorporate any new or additional requirements, no outside comment was required.

   For guidance that recommends new scientific or regulatory approaches which would affect a defined segment of the regulated industry, an opportunity for comment by

the affected parties would be appropriate. As an example, a guidance document which incorporates new testing procedures for diagnostic ultrasound equipment would necessitate input from the Center as well as appropriate trade associations and the affected firms.

Finally, guidance that represents significant changes to current practices or that raises complex or novel scientific or regulatory issues and that impacts a broad or ill-defined segment of the regulated industry may require substantial public participation. For example, the guidance document entitled, "Deciding When to Submit a 510(k) for a Change to an Existing Device" specifies those modifications to a device which would require submission of a 510(k). Because this document affects such a large segment of the regulated industry, FDA solicited public comment on the draft document by publishing a notice of availability in the Federal Register and through public meetings with device manufacturers. Following revisions, the availability of the final document will be announced in the Federal Register.

To facilitate the development of such guidance which poses significant changes to current scientific/regulatory practices or which poses new or complex scientific or regulatory approaches, staff should refer to the flowchart which was developed by the CDRH Science Advisory Group (*See* Attachment B). The flowchart was intended to serve as a general model of the guidance document developmental process and to provide flexibility to this process. For each of the steps in the flowchart, suggestions and examples for implementation of a particular step are provided; however, other approaches may also be appropriate.

2) When distributing a draft document for comment, the CDRH Draft Guidance Document Cover Sheet (*See* Attachment C) should be used to distinguish this document from one that is being released for actual use. A release date, contact name and address, and due date for comments must be specified on the coversheet.

At this time, the CDRH Draft Guidance Document Release Form (*See* Attachment D) should also be prepared and included in the draft guidance. This sheet documents the developmental process, ensures proper sign-off by senior office management, and provides key information to DSMA for incorporating the guidance document into the database. If the coversheet and release form are not included with the guidance document, the document may not be released for comment outside of the originating office.

3) When releasing a document for public comment, staff should consider the various avenues that are available. These include, but are not limited to, distribution to device manufacturers, distribution to trade associations, discussion at panel meetings, discussion at public meetings, distribution via the Division of Small

Manufacturers Assistance's (DSMA) Electronic Docket or FDA's World Wide Web Home Page, and publication of a Notice of Availability in the Federal Register.

Once the comment period has ended, the draft guidance document should be revised to incorporate/address the comments received. While FDA is not required to respond to each comment, the decision not to include any significant comments should be discussed with senior division and/or office management, as needed.

4) Upon completion of the "final" guidance document, the CDRH Final Guidance Document Cover Sheet (*See* Attachment E) should be prepared. As required by this sheet, a contact name and address and completion date must be specified. The CDRH Final Guidance Document Release Form (*See* Attachment F) should also be completed and forwarded with the guidance document for sign-off by senior office management. Once the office director has signed the release form, a hardcopy and diskcopy of the guidance document may be forwarded to DSMA for addition to the database. If the guidance document is to replace an earlier version, the title of the previous version should be clearly indicated on the coversheet to help ensure that users are apprised of the most recent version of the guidance document.

5) CDRH staff should keep in mind that all guidance documents are subject to public comment even after they become effective. In addition, the developmental process should be viewed as a continuous one in which guidance documents are periodically examined and updated in order to stay current.

C. Procedures Regarding the Proper Use of Guidance Documents

Above all, it must be recognized that CDRH guidance documents do no more than their name implies, i.e., provide guidance. One of the purposes of guidance documents is to assist the regulated industry in understanding FDA's interpretation of the statute and its implementing regulations. Some guidance documents provide the Agency's interpretation of the law and regulations so that compliance will be achieved and enforcement actions avoided. Others help to ensure consistency in the review process and to promulgate FDA's current position and/or concerns on a particular issue. Whatever form they may take, guidance documents do not confer legally enforceable rights or responsibilities on either the FDA or the public. Thus, they do not have the force of regulations and cannot serve to bind the regulated industry or the Agency in any manner. Therefore, when drafting or referencing a guidance document, staff should recognize that there may be several approaches to address a situation. The language used in citing a guidance document or in the guidance document itself should reflect this and thus should not be compulsory unless referring to a statutory or regulatory requirement.

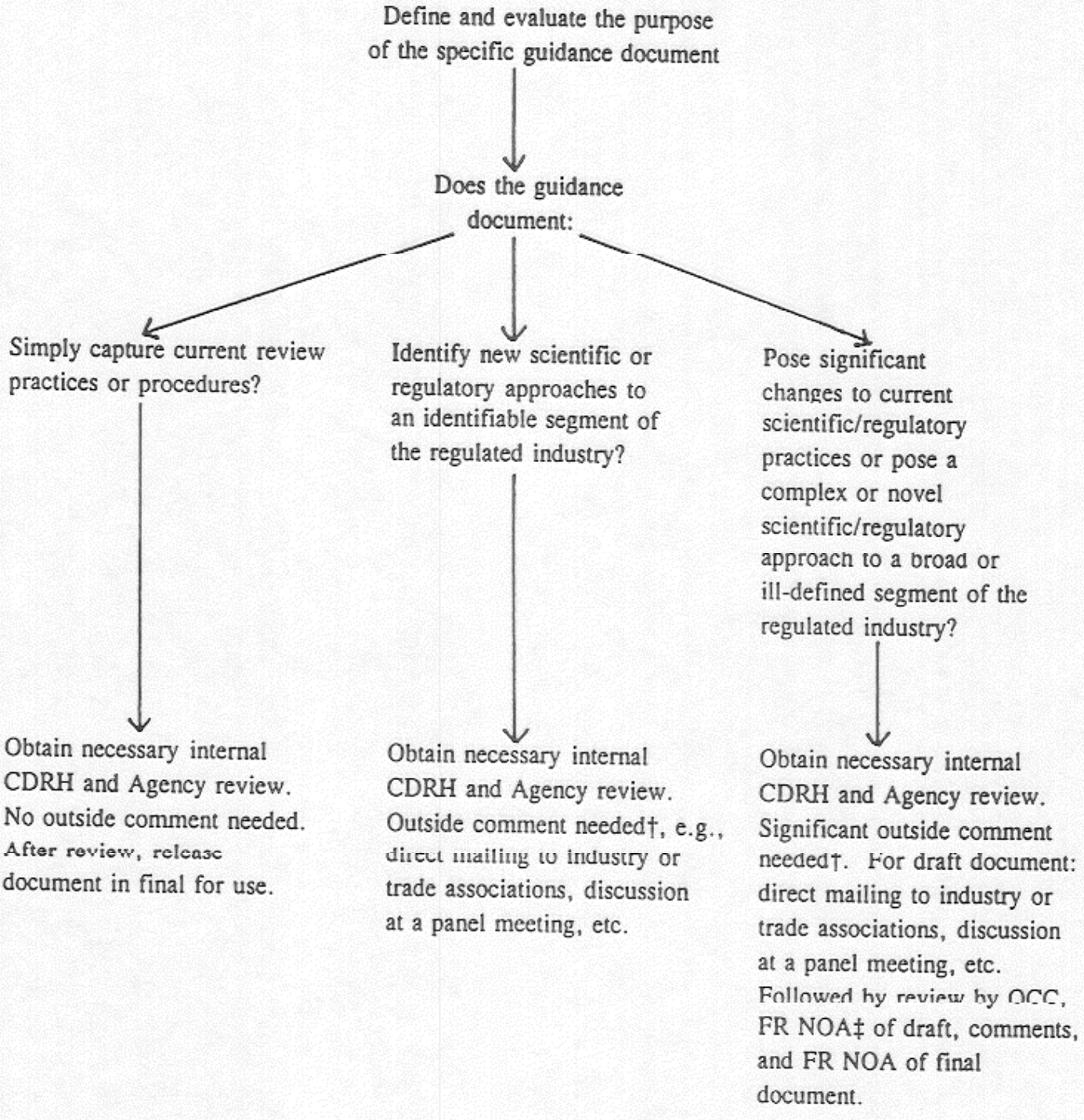
As these new procedures are implemented, CDRH will conduct various training exercises regarding "good guidance practices." This will include periodic seminars on this topic

which may be followed by a series of case-oriented workshops. CDRH staff should take advantage of this training which is important to both the Agency and the public. In addition, modifications to the Center's approach to the development and use of guidance documents may occur as the Agency considers the appropriate steps to take to promote consistency among the Centers.

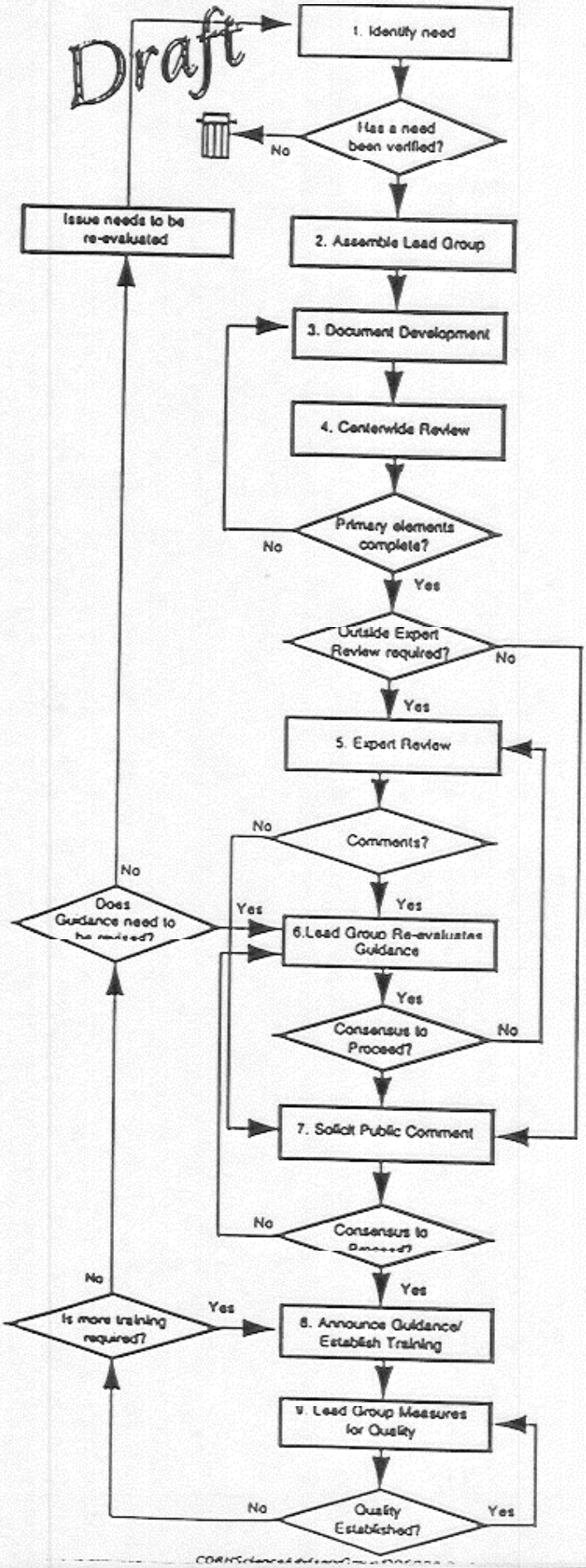
Elizabeth D. Jacobson, Ph.D.

Attachment A

Center for Devices and Radiological Health
Guidance Document Decision Tree



† The Science Advisory Group's flowchart may be used as a guide to approaches in obtaining public comment.
‡ NOA - Notice of Availability



1 - ODE takes lead on identifying issue or adopt issue recommended from other sources
- collect data, for example:
  - identify if there are cross cutting issues
  - review current review practice
  - assess quality of current review practice
- evaluate and verify need and determine if document requires large group participation or involves a smaller issue with limited Center involvement
- release findings to ODE staff for review and feedback
- establish a method to maintain record, e.g., shared folder

2. - identify issue-specific experts to lead issue-specific review process within CDRH if necessary.
  - assess what final outcome is needed of the guidance
  - define the scope and purpose of the guidance with respect to the desired outcome

3. - develop preliminary guidance document, for example:
  - internal guidance development
  - adopt or modify pre-existing industry standard
  - develop a collaborative approach to guidance development
  - request development of guidance by an external group via FR notice
- develop plan to institute guidance to staff
- establish means to measure for quality of proposed guidance

4. - ODE or CDRH sign off procedures
- vet to other offices in CDRH
- assess the impact of guidance

5. - vet to group of experts thru proper regulatory mechanisms appropriate for specific issue to establish if document is scientifically sound, for example:
  - panel members
  - agency experts
  - outside experts thru proper mechanisms (Part 15 Hearing, Public Workshop, Consultant clearance) from:
    - other agencies (e.g., NIST, NASA)
    - universities
    - industry
- present assessment and proposed guidance
- identify charge to group

6. - Lead group reviews comments and recommendations
- Lead group responds to comments
- Lead group revises proposed guidance
- Issue for final Centerwide review

7. - announce to staff and other stakeholders
- publish via FR notice, publications, internet, etc.
- present at panel meetings and conferences
- communicate with HIMA and other affected organizations

8. - ODE announces guidance & works w/Staff College to:
  - inform
  - educate
  - retrain
  - communicate

9. - Internal review for:
  - consistency
  - timeliness
  - value to sponsor
  - quality of questions from staff
  - accessibility of staff to sponsor
  - deviations:
    - are they appropriate?
    - are they needed?
  - release findings to review staff for feedback
- External review for:
  - evaluate if the guidance has achieved the desired outcome
  - evaluate if the document is current with the scientific community?

Attachment C

[CDRH Draft Guidance Document Cover Sheet]

[Guidance Document Title]
Draft Document

This guidance document is being distributed for comment purposes only.

[Identity of originating organization, including Branch, Division, and Office]

Draft released for comment on: [release date]

Comments and suggestions regarding this draft document should be submitted within [30/ 60/ 90] days of the above release date to [name and address (with mail code) of person to receive comments]. Comments and suggestions received after this date may not be acted upon by the Agency until the document is next revised or updated. For questions regarding this draft document, contact [name of contact person] at [phone number].

U.S DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health

Attachment D

CDRH Draft Guidance Document Release Form

Title of Draft Guidance Document: _____

_____

Keywords: (1) _____
(2) _____
(3) _____

Contact Person (Include phone number): _____

Originating Organization (Branch/Division/Office): _____/_____/_____

For Draft Guidance Documents:

- Internal Agency Organizations Having Reviewed Draft:

  ☐ ODE ☐ OST ☐ OSB ☐ Other
  ☐ OC ☐ OHIP ☐ OCC ☐ Not Applicable

  Remarks: _____

  _____

- Release Requested For Comments Via:
  - ☐ Regulated Industry and/or Trade Association;
  - ☐ Panel Discussion (Date: _____);
  - ☐ Electronic Docket (DSMA);
  - ☐ Federal Register;
  - ☐ Internet; or
  - ☐ Other (Specify: _____)

Branch Chief _____ ☐ Release ☐ Do Not Release _____
Signature (Date)

Division Director _____ ☐ Release ☐ Do Not Release _____
Signature (Date)

Office Director _____ ☐ Release ☐ Do Not Release _____
Signature (Date)

Attachment E

[CDRH Final Guidance Document Cover Sheet]

[Guidance Document Title]

This document is intended to provide guidance in the preparation of a regulatory submission. It does not bind the FDA or the regulated industry in any manner.

[Identity of originating organization, including Branch, Division, and Office]

Document Issued on: [date that document was signed-off by the office director]

While this guidance document represents a final document, comments and suggestions may be submitted at any time for Agency consideration by writing to [name and address (with mail code) of person to receive comments]. For questions regarding the use or interpretation of this guidance, contact [name of contact person] at [phone number]. [This guidance document replaces [title of previous version of guidance document] which was issued on [date].]

U.S DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health

CDRH Final Guidance Document Release Form

Title of Final Guidance Document: _____

_____

Keywords: (1) _____

(2) _____

(3) _____

Contact Person (Include phone number): _____

Originating Organization (Branch/Division/Office): _____/_____/_____

For Final Guidance Documents:

- Internal Agency Organizations Recommending Clearance:

  ☐ ODE ☐ OST ☐ OSB ☐ Other
  ☐ OC ☐ OHIP ☐ OCC ☐ Not Applicable

  Remarks: _____

  _____

- External Review Achieved Through:
  - ☐ Regulated Industry and/or Trade Association:
  - ☐ Panel Discussion (Date: _____);
  - ☐ Electronic Docket (DSMA);
  - ☐ Federal Register;
  - ☐ Internet; or
  - ☐ Other (Specify. _____)

Branch Chief _____ ☐ Release ☐ Do Not Release _____

Signature (Date)

Division Director _____ ☐ Release ☐ Do Not Release _____

Signature (Date)

Office Director _____ ☐ Release ☐ Do Not Release _____

Signature (Date)

NOTE TO DSMA: Upon receipt of a final guidance document, any existing draft document should be deleted from the database and replaced by the final document. (See CDRH Final Guidance Document Coversheet for title of the document to be replaced, if any.)